**Attorney Docket Number: MBIO1999-057CP2RCEM Serial Number: 09/503,387**

## REMARKS

Claims 26-29, 33-47, 53, 54, 65-79, and 87-90 were pending in this application as of the Office Action dated December 19, 2005.

Applicants have not amended nor canceled any of the claims, therefore claims 26-29, 33-47, 53, 54, 65-79, and 87-90 will be pending upon entry of this Amendment. The remarks made herein are designed to place the case in condition for allowance. As such, Applicants respectfully request that the remarks made herein be entered and fully considered.

## Double Patenting

Claims 26-29, 33-47, 53-54, 65-79, and 87-90 were "[p]rovisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44-58 of copending Application No. 10/850,034." Specifically, the Examiner asserts that "[a]n issuance of a patent to instant application would include the antibody of copending application 10/850,034."

Claims 26-29, 33-47, 53-54, 65-79, and 87-90 were also "[p]rovisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 252 and 265-277 of copending Application No. 09/610,118." Specifically, the Examiner asserts that "[a]n issuance of a patent to instant application would include the antibody of copending application 09/610,118."

Applicants respectfully traverse these rejections. The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. For the reasons described below, Applicants submit that the obviousness-type double patenting rejections are improper as no patent term extension or patent term adjustment is possible for the present application.

Applicants submit that the present application and co-pending applications 10/850,034 ('034 application) and 09/610,118 ('118 application) all claim priority to the same application,

namely U.S. Patent Application Serial No. 09/345,468 ('468 application), filed June 30, 1999, now U.S. Patent No. 6,245,527. This patent has a post-GATT filing date and therefore has a patent term of twenty years from filing, i.e. the patent will expire on June 30, 2019. Any applications claiming priority to this application which were filed prior to May 29, 2000 will also expire on June 30, 2019, as such applications are not entitled to patent term adjustment (37 C.F.R. 1.702(f) sections 1.703-1.705). Any applications which are filed on or after May 29, 2000 are entitled to patent term adjustment. Therefore, since the present application was filed on February 14, 2000, no patent term adjustment is possible and the application will expire on June 30, 2019, the same day as U.S. Patent No. 6,245,527. This expiration date is also prior to the expiration date of the '118 application, which issued as U.S. Patent No. 6,989,144, which was granted 21 days of patent term adjustment and will therefore expire on July 21, 2019. Therefore, Applicants submit that the obviousness-type double patenting rejection is improper.

In the event that the Examiner disagrees and is able to provide a mechanism by which an extension of exclusivity would be possible, Applicants submit that the Examiner would need to use a two-way obviousness test based on the facts of the present case to determine whether or not obviousness-type double patenting existed. Therefore, Applicants submit that the current obviousness-type double patenting rejections are improper because the Examiner improperly used a one-way obviousness test rather than a two-way obviousness test. In the context of genus and species claims, in the one way test, one asks if the genus anticipates or renders obvious the species and does the species anticipate or render obvious the genus. If the answer is yes to either inquiry, then the rejection is appropriate. Under the two-way test, the USPTO must show that the answer is yes to both inquiries. According to Eli Lilly v. Barr Laboratories (251 F.3d 955 (Fed.Cir. 2001)) the Federal Circuit stated in a footnote "The two-way test is only appropriate in the unusual circumstance where, inter alia, the United States Patent and Trademark Office ("PTO") is 'solely responsible for the delay causing the second-filed application to issue prior to the first'." Applicants submit that, in the event that the Examiner is able to provide a mechanism by which an extension of exclusivity would be possible for the present case, a two-way obviousness test should be applied to the present case as applications '034 and '118 were filed

after the present case and were both allowed first due to delays by the USPTO during prosecution of the present application.

The present application, which is drawn to anti-TANGO268 antibodies, was filed on February 14, 2000. The '034 application, which is drawn to specific single chain anti-TANGO268 antibodies, was filed on May 20, 2004. The '118 application, which is also drawn to specific single chain anti-TANGO268 antibodies, was filed on June 30, 2000 as a continuation-in-part of the present application. The three applications could not have been filed on the same day as the single chain antibodies had not been created as of the filing date of the present application. Under such a scenario, the claims of the present application represent the genus and those of the '034 and '118 applications represent species of the genus.

Despite the fact that the present application was filed before the '034 and '118 applications, the '034 application was recently allowed and the '118 application recently issued as U.S. Patent 6,989,144. Applicants submit that the delay in issuance of the present application was solely the responsibility of the USPTO. During prosecution of the present application, an Office Action was not received by Applicants, delaying the proceedings for a total of twenty one months. Specifically, an Office Action was sent by the USPTO on November 19, 2003. Applicants never received this Office Action and received a Notice of Abandonment on August 19, 2004. Applicants filed a Petition to Withdraw Holding of Abandonment on Failure to Receive an Office Action on September 10, 2004. The Petition was granted on December 22, 2004 stating that the "[a]pplication will be forwarded to the examiner for prompt mailing of a new Office Action". No such Office Action had been received by May 20, 2005, hence Applicants filed a Status Enquiry on May 20, 2005. The Office Action was then mailed on July 21, 2005.

Applicants therefore submit that the present application would have likely issued before the '034 and '118 applications had there not been any delays from the USPTO to re-issue the Office Action after the grant of the petition. According to Eli Lilly v. Barr (supra), a two-way obviousness test is applicable under the fact pattern of the present application. When applying a two-way obviousness test to the present scenario, one comes to the conclusion that the genus (i.e. anti-TANGO268 antibodies) does not anticipate or render obvious the species (i.e. single chain anti-TANGO268 antibodies), hence an obviousness-type double patenting rejection is improper.

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Therefore, Applicants submit that the obviousness-type double patenting rejection is improper because extension of patent exclusivity is not possible. Additionally, there was a significant delay by the USPTO during the prosecution of the present application, which caused the '034 and '118 applications to issue before the present application despite the fact that they were filed after the present application. Therefore, as per Eli Lilly v. Barr (supra), a two-way obviousness test applies. When applying a two-way obviousness test, one concludes that the genus does not anticipate or render obvious the species, hence an obviousness-type double patenting rejection is improper. Therefore, Applicants respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection over claims 44-58 of co-pending Application No. 10/850,034 and over claims 252 and 265-277 of co-pending Application No. 09/610,118.

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## CONCLUSION

In view of the amendments and remarks made herein, Applicants respectfully submit that the rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is believed that this paper is being filed timely and that a three month extension of time is required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

June 2, 2006

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